August 1, 2005

Vicente Santa Cruz, Ph.D.
Product Stewardship, Toxicology
Chevron Phillips Chemical Company LP
10001 Six Pines Drive
Suite 4103
The Woodlands, TX 77380

Dear Dr. Cruz:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Sulfonated Asphalt, Sodium Salt posted on the ChemRTK HPV Challenge Program Web site on May 18, 2004. I commend Chevron Phillips Chemical Company LP for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Chevron Phillips advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Sulfonated Asphalt, Sodium Salt

Summary of EPA Comments

The sponsor, Chevron Philips Chemical Company LP, submitted a test plan and robust summaries to EPA for Sulfonated asphalt, sodium salt (SAS; CAS No. 68201-32-1) dated April 29, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on May 18, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. The test plan does not adequately support the use of the analog data to satisfy the various endpoints. The test plan does not provide a detailed comparison of the components of the analogs and of the sponsored substance, nor show how the analogs will reasonably represent SAS.

2. Physicochemical Properties. The submitted data for melting point, boiling point, vapor pressure and partition coefficient are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to provide robust summaries for these endpoints. EPA agrees with the submitter's proposed water solubility testing of SAS.

3. Environmental Fate. The submitted data for these endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide a robust summary for photodegradation and include a stability in water discussion in the robust summary.

4. Health Effects. The submitted acute toxicity data are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproductive/ developmental toxicity screening test and an *in vitro* genetic mutation (Ames) test. EPA reserves judgement on the adequacy of analog data for the chromosomal aberration endpoint until the submitter provides adequate analog justification. The submitter also needs to address robust summary deficiencies.

5. Ecological Effects. EPA reserves judgement on the adequacy of the data for these endpoints pending submission of the water solubility data on SAS.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Sulfonated Asphalt, Sodium Salt Challenge Submission

Test Plan

Analog Justification

The test plan does not adequately support the use of the analog data. Especially needed is additional quantitative information about the composition of the mixtures that includes typical ranges of the amounts of each of the components in the mixtures, and sufficient information to compare the composition of SAS with the analogs. The test plan lacks a detailed comparison of the components of the analogs and of the sponsored substance, and does not show how the analogs will reasonably represent SAS in tests for the mammalian toxicity endpoints. For ecotoxicity, species differences also hindered comparison of data between analogs and SAS. EPA refers the submitter to the guidance on EPA's ChemRTK HPV Challenge Program website at http://www.epa.gov/opptintr/chemrtk/guidocs.htm. Further, the analogs cited are all the subject of other submissions to the HPV Challenge program (and were so referenced in the current submission); EPA refers the submitter to EPA's comments and data adequacy reviews on these analog HPV Challenge submissions

(http://www.epa.gov/chemrtk/asphlcat/c14901tc.htm, http://www.epa.gov/chemrtk/resbscat/c14906tc.htm, http://www.epa.gov/chemrtk/alklsulf/c13206tc.htm).

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility)

The submitted data for melting point, boiling point, vapor pressure, and partition coefficient are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to provide robust summaries for these endpoints.

Water Solubility. EPA agrees with the submitter's plan to perform a water solubility test for SAS. The submitter needs to incorporate these data into the robust summaries.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for photodegradation, biodegradation, and fugacity are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to provide a robust summary for photodegradation.

Stability in water. Although EPA agrees with the submitter that these chemicals are not susceptible to hydrolysis, the submitter needs to provide this discussion in a robust summary.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted data for acute toxicity are adequate for the purposes of the HPV Challenge Program. The submitter has provided analog data on some endpoints and also has proposed testing for repeated-dose, reproductive and developmental toxicity (OECD TG 422) and genetic toxicity (OECD TGs 471) endpoints. EPA agrees with the proposed testing. However, unless the submitter provides adequate analog justification and demonstrates that the composition for SAS and the analog are comparable, the submitter needs to provide data for the chromosomal aberration endpoint on SAS according to OECD TG 473.

Ecological Effects (fish, invertebrates, algae)

Although the acute aquatic toxicity data submitted for fish, invertebrates and algae are inadequate (e.g., use of nonstandard species), SAS's log K_{ow} and water solubility properties may render further testing unnecessary for the purposes of the HPV Challenge Program. Therefore, EPA reserves judgement on the adequacy of these endpoints pending submission of the water solubility data.

Specific Comments on the Robust Summaries

Health Effects

Acute Toxicity (Oral). In the first robust summary, the submitter needs to replace LC50 with LD50. In both summaries, the submitter needs to provide more complete information on the number of animals per dose that exhibited the effects seen.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.